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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,669	BRINGE ET AL.	
	Examiner	Art Unit	
	ABDEL A. MOHAMED	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-11,14,28-32 and 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15-27,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/21/05,9/5/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO remains the same. To aid in correlating any papers for this application, all further correspondence regarding to this application should be directed to Examiner Abdel A. Mohamed.

ACKNOWLEDGEMENT OF AMENDMENT, REMARKS IDS AND STATUS OF THE CLAIMS

1. The amendment, remarks filed 06/03/08 and the information disclosure statements (IDS) and Forms PTO-1449 filed 10/21/2005 and 09/05/08 are acknowledged, entered and considered. In view of Applicant's request claims 26 and 28 have been amended and claims 1-55 are now pending in the application of which claims 1-11, 14, 28-32 and 35-55 are withdrawn as non-elected invention. Claims 12, 13, 15-27, 33 and 34 are currently under examination as *per* elected invention. The objection to the claims and the rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 06/03/08. Applicant's remarks with respect to the rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 103(a) over the prior art of record have been considered but deemed to be moot in view of the new grounds of rejections.

NEW GROUNDS OF REJECTIONS

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 13, 15-27, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a formulation of glycinin and/or beta-conglycinin as well as an isolated soy material and an isolated oil body associated protein in the presence or absence of at least one additive compound may be combined to form a composition of the invention, such as soy protein with mammalian lipoprotein for lowering cholesterol, does not reasonably provide enablement for a composition for treating or preventing hypercholesterolemia comprising beta-conglycinin, or fragment thereof and an oil body associated protein wherein the beta-conglycinin and the oily body associated protein are present in an amount effective to provide a synergistic effect for the treatment or prevention of hypercholesterolemia as recited in claims 12, 13, 15-27, 33 and 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification provides eight different sequence fragments of ß-conglycinin and provides guidance as to high molecular weight fraction (HMF) of soy

proteins. The specification provides enriching crude plant proteins with an isolated oil body protein1, 10, 100, 200, 1000 or more times or 1, 5, 10, 50, 100 or more fold relative to a purified fraction such as HMF. Page 14 of the instant specification further provides that oil body associated proteins are added to a final concentration of about 0.5%, 1%, 3%, 10%, 20% or more by weight including all intermediate ranges within these concentrations. The specification on page 20 discusses isolating mammalian lipoprotein but not any particular one. However, the specification on pages 20-21 does discuss egg yolk lipoproteins, separately. Nevertheless, the above compositions, exemplify ß-conglycinin and mammalian lipoproteins, wherein a vast plethora of these compositions were not tested for lowering cholesterol and neither synergy nor prevention was ever shown. Additionally, since the compositions only refer to mammalian lipoproteins, one does not know if one or many mammalian lipoproteins were used. Nor does one know which mammalian lipoprotein(s) were used. Further, as admittedly acknowledged on page 18 in the instant specification, most eukaryotic cells from species such as plants, mammals, non-mammalian cells, algae and yeast contain intracellular lipid particles with associated proteins embedded. Each mammal would have its own lipoproteins, which like the oleosins would differ from species to species. Furthermore, as stated on page 6, lines 24-29 in the instant specification oil bodies are typically comprised of triacylglycerides and surrounded by lipoproteins and proteins. An "oil body associated protein" includes any and all of these proteins and lipoproteins which are physically associated with oil bodies. In plants, the major oil body associated proteins are oleosins.

Thus, there is at least one protein and probably more associated with each species. The examples include making fragment high molecular fraction, trypsinization fragments (but no sequences set forth so we don't know if there is overlap with the eight SEQ ID NOS provided). Isolating the components of the HMF to include the alpha, alpha' and beta subunit of beta glycinin, where many peptides were produced with trypsinization (in Example 1). The effect of HMF on cholesterol uptake was set forth in Example 2. HMF was tested alone and not in conjunction with any oil body protein. Thus, the only guidance provided by Applicant is to combine mammalian lipoproteins with various isolated soy proteins with wide ranges of oil body associated proteins for inclusion. No specific guidance is provided with respect to mammalian lipoproteins, only egg yolk lipoprotein was provided. No specific guidance is provided with respect to the cholesterol lowering properties of individual fragments; the specification just sets forth eight sequences obtained from trypsinization. No specific guidance is provided for creating synergistic amounts. Synergy is only mentioned in the specification as it relates to being present. No specific guidance as to the amounts, which particular proteins exhibit synergy. No example(s) are provided of any synergistic compounds. No specific guidance is provided with respect to the fragments of beta conglycinin. Eight potential fragments and the subunits are disclosed but their relationship to each other and their use for cholesterol lowering has not been determined. Thus, the specification does not provide any example of formulations displaying synergy, cholesterol lowering or hypercholesterolemia treatment/prevention by using the fragments claimed. The claims are very broad because they refer to any fragment (2 or

more amino acids) of beta conglycinin, which has 3 different subunits. They literally read upon millions of compounds.

With respect to providing a synergistic effect for treatment or prevention of hypercholesterolemia, it is known in the art that synergy is a confusing topic and is profusely littered with technical terms that are not always clearly defined (M.C. Berenbaum, Clin. Exp. Immunol., Vol. 28, pp 1-18, 1977, referred as Berenbaum 1) and (M.C. Berenbaum, Pharmacological Reviews, Vol. 41, pp. 93-141, 1989, referred as Berenbaum 2). Berenbaum teaches that the basic difficulty is that most investigations use fallacious criteria for determining the nature of drug interactions. They compare the effect of the agents used in combination with the sum of their effects when used alone (See e.g., Berenbaum 1 page 1 and Berenbaum 2 page 95, respectively). However, while this comparison is experimentally straight-forward, it is based on assumptions that are wrong, it leads to endless confusion, and conclusions based on it are generally valueless (See e.g., Berenbaum 1 page 1 and Berenbaum 2 page 95, respectively). Berenbaum states that the correct method for analyzing drug interactions is, in most cases, more laborious and involved, but conclusions upon which it is based are reliable (See e.g., Berenbaum 1 page and Berenbaum 2 pages 95-96, respectively). Berenbaum describes synergy as a combination of agents that is more effective than expected from the effectiveness of its constituents and one less effective describes antagonism and thus synergy and antagonism imply that the different constituents effect each other's actions, i, e., they interact pharmacologically; additivism implies that they do not (See e.g., Berenbaum 1 pages 1-2 and Berenbaum 2 pages 95 and 98,

respectively). Berenbaum sets forth the problems with current methods of determining synergy and sets forth a method of determining synergy that overcomes these problems for both homoergic and heterergic combinations (See e.g., Berenbaum 1 pages 2-8 and Berenbaum 2 pages 95-131). Berenbaum then describes the minimum requirements for demonstrating synergy, additivism or antagonism (See e.g., Berenbaum 1 pages 8-12 and Berenbaum 2 pages 100-116, respectively). Berenbaum then describes the clinical implications of searching for synergy and the advantages that can result, such as cost and potential shortage of drugs (See e.g., Berenbaum 1 pages 16-17 and Berenbaum 2 pages 100-116 and 125-130, respectively). Note that the current state of the art has not changed with respect to synergy because Ronald J. Tallarida discusses synergy based on the same theory of Berenbaum 1 and Berenbaum 2 cited above. For example, see the book of Ronald J. Tallarida, titled Drug Synergism and Dose Effect Data Analysis. Published by Chapman & Hall/CRC on 2000. Thus, in view of the above and in view of what is known in the art, synergy is unpredictable and the claims are not commensurate in scope with the showing of the specification.

In regard to preventing hypercholesterolemia, the hypercholesterolemia may be influenced by a variety of factors, such as diet, genetics, amount of exercise, other diseases and/or situations/conditions contributing to hypercholesterolemia, for example, diabetes, hypertension, obesity, etc. The ability to prevent, i.e., to keep from happening requires that one knows all the risk factors and the ability to predict which members of the populace will get the disease. As there is sometimes a genetic component and there is no current screening for the gene(s), this populace can not be elucidated before

the individual has high cholesterol. Prevention becomes unpredictable. With respect to synergy, it is not predictable because one must test the compounds in order to know if there is synergy and the sheer number of fragments creates an exponential issue.

Therefore, in view of the above, considering the state of the art as discussed by the references, the unpredictability of synergy and prevention of hypercholesterolemia and the lack of guidance provided in the specification with regards to proportions providing synergy, the cholesterol lowering effect of the fragments, the lack of a consensus sequence or necessary amino acids in the fragments, one of ordinary skill in the art would be burdened with undue experimentation to determine synergistic formulations, effective fragments, particular mammalian lipoproteins that lower cholesterol, and prevention. One would even have to show that synergy exists for these formulations, including the millions of fragments of beta-conglycinin with all of the different oily body proteins, including all of the different plant specific oil body proteins, the various amino acids and lipoproteins disclosed and contemplated. Thus, there are no indicia that the present application enables the full scope in view of synergistic effect and in view of preventing and using the claimed agents as discussed in the stated rejection. The present application provides no indicia and no teachings/guidance as to how the full scope of the claims is enabled.

Thus, the scope of the instantly claimed invention is very broad and speculative. Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of pharmaceutical composition in all kinds of possible compounds are contemplated and

are encompassed as well as wide range of situations, wherein the synergistic effect and the prevention encompasses human patients suffering from hypercholesterolemia as claimed in the instant specification. The results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed. Hence, one of ordinary skill in the art would not be able to show or demonstrate the enablement to a composition for treating or preventing hypercholesterolemia comprising glycinin and/or beta conglycinin, or fragments thereof and oil body associated protein, wherein the glycinin and/or beta conglycinin and the oil body associated protein are present in an amount effective to provide a synergistic effect for the treatment or prevention of hypercholesterolemia in a subject in need thereof as recited in claims 11, 13, 15-27, 33 and 34. Thus, Applicant has not established any *nexus* between all kinds of pharmaceutical compositions and their use in the manner claimed.

Further, the first paragraph of 35 U.S.C. 112 requires, *inter alia*, that a patent specification provide sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, id. At 496, 20 USPQ2d at 1445, it is well settled that "the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification". *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Where practice of the full scope of the claims would require experimentation; factors to be considered in determining whether a disclosure would require undue experimentation ..... include (1) the

quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Therefore, in view of the above, and in view of the fact that there is no enablement in the instant specification for all kinds of pharmaceutical compositions having synergistic effect for the treatment or prevention of hypercholesterolemia in a subject including human in the manner claimed in the claims of the instant invention. Thus, applying the *Wands* factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working example(s) or data, and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is suggested.

CLAIM REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 15, 20, 21, 26, 27, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bringe (U.S. Patent No. 6,171,640 B1).

Bringe ('640 patent) discloses a composition comprising a high beta conglycinin and/or glycinin in combination with oil body associated protein such as soy protein ingredients having cholesterol and triglyceride lowering properties. The '640 patent defines soy protein composition to refer to food ingredients for humans or animals which contain soy proteins. Examples include soy flour, defatted soy flour, spray dried soymilk, tofu, spray dried tofu, soy protein concentrate, texturized soy protein concentrate and hydrolyzed soy protein and soy protein isolate (See e.g. col. 5, lines 41-48 and col. 8, lines 56-67). The '640 patent also discloses the differences between casein protein (animal protein) and soy protein (vegetable protein), wherein the casein is phosphorylated. Also, the reference states that in animal casein, the beta-conglycinin is a glycoprotein which contains covalently attached carbohydrates and its solubility is improved by partially hydrolyzing beta-conglycinin using an enzyme such as Alacalase (See e.g., cols 16 and 18). The reference further includes various additives such as egg yolk lipoprotein, egg white and isoflavin (See e.g., cols. 7, 11 and Tables 8 and 9). Thus, clearly disclosing a composition comprising soy material in combination with oil body associated protein and additive compounds thereof as directed to claims 12, 13, 15, 20, 21, 26, 27, 33 and 34.

With respect to synergistic affect, the Examiner acknowledges that the '640 patent does not recite the synergistic affect of claimed composition. However, the reference shows **positive correlation** which could be interpreted as **synergism** by stating on col. 4, lines 22-27 that yields of protein and other soybean constituents also need to be considered in designing a commercially viable variety. Positive correlations were found between total protein content of soybeans and the glycinin-beta-conglycinin ratio, so the soybeans that were richer in glycinin had a higher protein content. Thus since the reference's composition and the claimed composition have substantially the same components, synergism is considered as a functional limitation which inherent in both situations.

In regard to preamble of claim 1 which states "A composition for treating or preventing hypercholesterolemia", the cited reference above does not disclose the intended use of the product/composition as claimed; although, the reference under the heading on col. 13 states "Cholesterol and triglyceride lowering properties of BC-SPI"; nevertheless a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that

property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed product/composition comprising soy material in combination with an oily body associated protein and additive compound thereof as taught by the reference anticipates claims 12, 13, 15, 20,21, 26, 27, 33 and 34 as drafted.

CLAIMS REJECTION-35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13, 15-27, 33 and 34 are rejected under 35 U.S.C. 102(b) as being unpatentable over Bringe (U.S. Patent No. 6,171,640 B1) taken with Kelly (U.S. Patent No. 5,830,887), Fiordaliso et al (Lipids, Vol. 30, No. 2, pages 163-167, 1995) and Hori et al (Biosci. Biotechnol. Biochem., Vol. 65, No. 1, pages 72-78, 2001).

The primary reference of '640 patent discloses as set forth above. However, the '640 patent differs from claim 22 in not teaching the additional ingredients of soybean saponins, subgroup phytoestrogens, subgroup isoflavones, particularly the isoflavone daidzein. The secondary reference of Kelly ('887 patent) discloses compositions enriched with natural phytoestrogens, particularly genistein, daidxein, etc. that are useful for treating hypercholesterolemia by lowering cholesterol, including LDL and VLDL (See e.g. abstract, col. 5, lines 53-66, col. 6, lines 15-18, col. 6, lines 29-56, cols. 10-11, claims 1, 3-9 and 11-13). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the preferred isoflavone combination of daidzein and genistein of the secondary reference of '887 patent to the primary reference of '640 patent teachings beta-conglycinin and body associated protein because it is *prima facie* obvious as the idea of combining them flows logically from their having been individually taught in the prior art for the same purpose (See MPEP 2144.06 and *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, 1072 [CCPA 1980]).

In regard to the limitations of claim 23, the primary reference of '640 patent fails to disclose the additional ingredient of carbohydrate substantially resistant to digestion,

specifically oligofructose. However, Fiordaliso discloses that the daily administration of oligofructose supplemented containing diet decreases plasma triglyceride, phospholipids and cholesterol (See abstract, pages 163, 165-167, Tables 1 and 2, Figures 2 and 3). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the preferred carbohydrate substantially resistant to digestion, specifically oligofructose of the secondary reference of Fiordaliso to the primary reference of '640 patent teachings beta-conglycinin and body associated protein because it is *prima facie* obvious as the idea of combining them flows logically from their having been individually taught in the prior art for the same purpose (See MPEP 2144.06 and *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, 1072 [CCPA 1980]). Further, it would have been obvious to one of ordinary skill in the art to which this invention pertains to have added the preferred carbohydrate substantially resistant to digestion, specifically oligofructose of the secondary reference of Fiordaliso to the synergistic effect of beta-conglycinin and soy protein of the primary reference of '640 patent because it also lowers cholesterol, and one would have the added benefit of lowering triglycerides.

The secondary reference of Hori teaches that the binding of phospholipid to soy protein hydrolyzate in large quantities brings stronger cholesterol-lowering effects (See e.g., pages 72-76, Figure 2 and Table 2). Further, on page 76 Hori discloses that lecithinated textured vegetable protein reduced serum total cholesterol. Thus, the reference clearly teaches the use of additional ingredients such as phospholipids,

lecithin, etc. for decreasing cholesterol levels in serum and as such meets the limitations of claim 24.

With respect to the percentages of oil body associated proteins recited in claims 16-19, the primary reference of '640 patent on col. 9 discloses various percentages and states that one of ordinary skill in the art would know how to optimize the necessary amount and would be able select other types of soy protein according to the need thereof.

Therefore, in view of the above, and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known composition for the intended purpose of treating or preventing hypercholesterolemia comprising beta-conglycinin or glycinin, or fragments thereof and an oily body associated protein, wherein the beta-conglycinin and the body associated protein are present in an amount effective to provide a synergistic effect for the treatment or prevention hypercholesterolemia, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABDEL A. MOHAMED whose telephone number is (571)272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657